IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF MELVIN ANHALT, M.D.

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Anhalt is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Ethicon has not satisfied this burden. Plaintiffs submit this Reply in support of their Motion to limit the opinions of Dr. Anhalt.

ARGUMENT

1. Dr. Anhalt lacks the requisite qualifications to opine on mesh design and materials.

Dr. Anhalt's testimony reveals his lack of qualifications with respect to the design of the mesh:

> **Q. Okay. All right. And you had mentioned just a couple minutes ago that you're not a scientist and you're not a materials person, your focus is on treating patients. Correct?**
> **A. Correct.**
> **Q. Okay. And have you ever participated in the design of a pelvic mesh sling?**
> **A. No.**
> **Q. Okay. Have you ever done any bench research**

with respect to polypropylene mesh?
A. No.
Q. Have you ever done any lab research with respect to polypropylene mesh?
A. No.
Q. Have you ever done any work with respect to preparation of labels for medical devices?
A. No.
Q. Have you done any work with respect to drafting warnings with respect to medical devices?
A. No.
Q. Have you done any work with respect to drafting instructions for use for medical devices?
A. No.
Q. Okay. And when I say medical devices, I'm also -- do you understand that that would also include female pelvic mesh?
A. Yes.
Q. Okay. Have you ever participated in drafting training materials for other physicians with respect to pelvic mesh?
A. No.
Q. Have you ever prepared a device history file?
A. I don't even know what that means, so apparently not.
Q. Okay. Have you participated in drafting any documents regarding risk analysis with respect to the design of pelvic mesh products?
A. No.

See Plaintiffs' Mem., Exhibit D, 59:9-60:16. Defendants chose, however, to ignore this testimony. Instead, Defendants suggest that Dr. Anhalt's background in treating patients sufficiently qualifies him as an expert on product design and polypropylene. Def. Resp. p. 4. However, even Dr. Anhalt acknowledges that he is not an expert and is not offering opinions specific to mesh design and polypropylene. *See* Plaintiffs' Mem. pp. 4-5. Furthermore, Dr. Anhalt disavows any specific knowledge regarding pore size, which is a significant element of the product design:

Q. Okay. Have you from a clinical standpoint, have you done any work with the smaller pore mesh?

A. No.
Q. Okay. Have you -- do you have –y knowledge regarding the difference in pore size between the Monarc mesh that you use and the TVT or TVTO?
A. I've just seen an article or two written about it, but I don't have an opinion on it.
Q. Okay. And you haven't participated in any studies regarding the pore size of mesh. Is that correct?
A. Correct.
Q. Okay. And you haven't authored any articles regarding pore size of mesh?
A. Correct.

See Plaintiffs' Mem., Exhibit D, 152:4-153:15.

This Court has previously excluded expert testimony concerning mesh design when the expert similarly lacked the requisite qualifications. *Tryee v. Boston Scientific*, 54 F.Supp.3d 501, 581 (S.D.W.V. 2014). The mere fact that Dr. Anhalt has design "preferences" as a practicing doctor in itself does not render him an expert in product design. *Id*. In *Tyree*, the Court distinguished between proposed experts who both had experience treating patients with mesh but only one had experience with product design (e.g., comparisons of Dr. Ostergard and Dr. Culligan). *Id*. In sum, the Court concluded that only the expert with specific experience concerning mesh design was qualified to render an opinion regarding design issues and, thus, there was no reason to address the reliability of Dr Culligan's opinions. *Id*. The same holds true in the present case. Like Dr. Culligan in *Tyree*, Dr. Anhalt lacks the requisite qualifications and his opinions regarding mesh design, including polypropylene materials, and porosity, should be excluded. *Id*.[1]

[1] Defendants suggest that Dr. Anhalt's experience and review of clinical literature sufficiently qualifies him as an expert on product design, materials etc. However, Defendants overstate this Court's conclusion in *Tyree*. Specifically, in *Tyree*, Dr. Green planned to testify that he has not seen "evidence of polypropylene degradation, systemic infection, or other unexpected reactions" in the course of his treatment of patients and, this Court allowed this limited opinion. *Tyree*, pp.

Finally, Dr. Anhalt testified that he is not rendering any opinions regarding the degradation, reactiveness, flaking, pore size, or roping of mesh. Plaintiffs' Mem., pp. 4-5. Thus, Dr. Anhalt should not be allowed to render such opinions at trial. *See Tyree* at p. 583.

2. Dr. Anhalt's Opinions Regarding Clinical Trials Should Be Excluded.

Dr. Anhalt is similarly unqualified to render opinions regarding clinical trials. Indeed, Dr. Anhalt testified that he clinical trial experience is limited at best and virtually non-existent with respect to mesh:

Q. Okay. Have you been involved in any clinical trials with respect to pelvic mesh products?
A. No.

Q. Okay. And so you have not done any clinical trial work comparing mid urethral to other pelvic procedures?
A. No, not formally.

Q. Okay. Have you ever been involved in the clinical trial comparing pelvic or organ prolapse mesh repair to other types of pelvic procedures?
A. No.

Q. Are you currently working at any clinical studies?
A. No.

Q: Have you done any clinical studies with respect to other types of medical devices?
A. No.

See Plaintiffs' Mem., pp.7-8 and Exhibit D, 68:11-24; 69:9-11. Thus, Dr. Anhalt is forced to rely solely on articles that he has reviewed. However, even Dr. Anhalt concedes that he has only

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585-586. Here, Defendants seek to proffer Dr. Anhalt for opinions that far exceed the limited scope of Dr. Green's opinions in *Tyree*. Also, unlike Dr. Green in Tyree, Dr. Anhalt has specifically testified that he is not rendering opinions with respect to degradation, reactiveness of polypropylene, roping, flaking, or pore size. *See* Plaintiffs' Mem., pp. 4-5.

reviewed summaries of the articles. See Plaintiffs' Mem., p. 7; Exhibit D, 40:2-15. Thus, even if Dr. Anhalt were qualified to render opinions regarding the adequacy of the clinical studies, his methodology and, therefore, the reliability of such opinions are lacking.

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Anhalt is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in Dr. Anhalt's opinions, Ethicon cannot carry this burden and Dr. Anhalt's testimony should be excluded and/or limited as set forth herein.

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CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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